



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,390	09/14/2004	Willem Van Dijk	2005-1025	9012

466 7590 04/14/2010
YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER

CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
----------	--------------

1655

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/14/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/500,390	Applicant(s) VAN DIJK ET AL.	
	Examiner CATHERYNE CHEN	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-44, 48-50 and 52 is/are pending in the application.
- 4a) Of the above claim(s) 31-34, 38 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 35-37, 39, 41-44, 48-50, 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on Dec. 28, 2009 has been entered.

Currently, Claims 27-29, 31-44, 48-50, and 52 are pending. Claims 27-29, 35-37, 39, 41-44, 48-50, and 52 are examined on the merits. Claims 1-26, 30, 45-47, and 51 are canceled. Claims 31-34, 38, and 40 are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29, 35-37, 39, 41-44, and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27, line 6, recites "and % other monosaccharides." The amount of monosaccharides is missing. What is the amount of monosaccharides?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-29, 35-37, 39, 41-44, 48-50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qiu et al. (US 6133440) in view of Strickland et al. (US 5824659), Yaron et al. (1992, J Agric Food Chem, 40: 1316-1320), Vilkas et al. (1986, Biochimie, 68: 1123-1127) and Shand et al. (US 5902796).

Qiu et al. teaches a composition of matter comprised primarily (>95%) of polysaccharides derived from Aloe, where the polysaccharides have average molecular weight of 70~80 kDa with a range between 50~200 kDa, and the polysaccharide are comprised of D-galactose (approx. 5% or less), D-glucose

Art Unit: 1655

(approx. 5% or less) and D-mannose (approximately 90%) (Claim 1). The composition of matter from Aloe species extracted and filtered (Claim 4). Aloe barbadensis gel was extracted (column 8, line 7). Aloe vera is also known as aloe barbadensis (see page 1, line 2, <http://www.thegardenhelper.com/aloe~vera.html>). Aloe products have been used in dermatological applications (column 1, lines 38-39). Aloe extracts have anti-inflammatory activity (column 1, lines 42-53). Aloe products are used in cosmetic industry to protect skin (column 2, lines 6-7). Galactose is another type of monosaccharide.

However, it does not teach 30-10% D-glucose, the ratio of mannose and glucose at about 5:1-20:1, positively charged columns, a food supplement, an oral dosage as a tablet, capsule, and syrup, and an injectable dosage.

Shand et al. teaches bioactive factor produced, isolated and separated from aloe vera for use in cosmetic, health food drink or topical ointment (column 1, lines 8-11, 37-40), where the filtered starting material is subjected to a separation using anion exchange chromatography with DEAE Sepharose (column 8, lines 50-54). Improper processing procedures contain no bioactive chemical ingredients (column 1, lines 41-43). Applicant's Specification teaches DEAE Sepharose is a positively charged column (page 3, lines 10-11).

Shand et al. teaches bioactive factor produced, isolated and separated from aloe vera for use in health food drink. Thus, it would be obvious to formulate aloe vera into a food as oral dosage, such as that taught by Shand et al. An artisan of ordinary skill would clearly expect that the oral dosage can

Art Unit: 1655

encompass a tablet, capsule or syrup would function successfully to administer the aloe vera as a food or drink taught by Shand et al. This reasonable expectation of success would motivate the artisan to modify aloe vera to include oral dosage as an effective means to administer the aloe vera extract.

Shand et al. teaches bioactive factor produced, isolated and separated from aloe vera for use in cosmetics. Thus, it would be obvious to formulate aloe vera into an injectable dosage, such as that taught by Shand et al. An artisan of ordinary skill would clearly expect that the injectable dosage would function successfully to administer the aloe vera as a cosmetic taught by Shand et al. This reasonable expectation of success would motivate the artisan to modify aloe vera to include injectable dosage as an effective means to administer the aloe vera extract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use positively charged column because aloe vera bioactive factor needs proper processing with positively charged column as taught by Shand et al. One would have been motivated to isolate bioactive factors from aloe vera with positively charged columns for the expected benefit of purifying bioactive factors from aloe vera. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

As for the concentrations, Strickland et al. teaches polysaccharide from aloe extract is about 7% glucose, about 85% mannose, and about 4% galactose

Art Unit: 1655

(Abstract). The dominant polysaccharide of *Aloe barbadensis* is glucomannan, which has glucose to mannose ratio of 1:4.5 (column 4, lines 39-31, 41).

As for the concentrations, Yaron et al. teaches aloe vera gel isolated by centrifugation (Materials and Methods, Preparation of Aloe vera gel), where the polysaccharide is made of 60.2% mannose, 22.2% glucose, and 1.6% galactose (Table 1).

As for the ratio of mannose to glucose, Vilkas et al. teaches mannose/glucose ratio for Fraction III at 7:2 (Table 1) by isolating from aloe and filtering in DEAE anion exchange column (Abstract).

MPEP 2144.05 Obviousness of Ranges

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation
Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc.,

Art Unit: 1655

874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Thus, through routine experimentation, “[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” In other words, the claimed amounts were well within the purview of the ordinary artisan at the time the invention was made in an effort to optimize the desired results.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michele Flood/
Primary Examiner, Art Unit 1655